CIRCULAR LETTER: DHCQ 12-98-385

TO: Hospital Administrators
FROM: Paul I. Dreyer, Ph.D., Director, Division of Health Care Quality
DATE: December 7, 1998
RE: Hospital Reporting of Serious Incidents

The purpose of this letter is to remind hospitals following our letter of May 1995 of their obligations to report incidents that seriously affect the health and safety of patients to the Department. The Department's regulation governing the reporting of incidents states that: *Hospitals must report fire, suicide, serious criminal acts, pending or actual strike, serious physical injury resulting from accident or unknown cause, and other serious incidents that seriously affect the health and safety of patients (105 CMR 130.331).*

The Department uses the following definitions as a guide for determining what needs to be reported:

- "Serious injury" means injury that is life threatening, results in death, or requires a patient to undergo significant additional diagnostic or treatment measures.
- "Accidents" includes falls, burns, electrocutions, and other misadventures not related to patient treatment.
- "Other serious incidents that seriously affect the health and safety of patients" means incidents that result in serious injury. These include, but are not limited to, poisonings occurring within the facility; reportable infectious disease outbreaks, equipment malfunction or user error, medication errors, and other incidents resulting in serious injury not anticipated in the normal course of events.
- Please refer to the list below of examples for guidance in deciding which incidents are reportable to the Department.

Examples of Reportable and Non-Reportable Incidents

Reportable Incidents - include, but are not limited to the following:

- Medication errors including, major I.V. therapy errors such as wrong rate or route, with serious complications (e.g., resulting in death, paralysis, coma, or permanent injury)
- Burns (e.g., hot liquids, equipment, hot packs)
- Slips or falls occurring within the facility that result in serious head injury, coma or permanent injury; or requiring significant additional therapeutic intervention or extended hospitalization.
- Major biomedical device or other equipment failure resulting in serious injury or having potential for serious injury to a patient, visitor, or employee. This would include user errors, as well as those device failures that must be reported to the U.S Food and Drug Administration pursuant to the Safe Medical Device Act.
- Surgical errors involving the wrong patient, the wrong side of the body, the wrong organ or the retention of a foreign object (e.g., sponge or clamp)

- Blood transfusion errors (e.g., wrong type of blood, outdated blood, blood not given when ordered, given to wrong patient, HIV seropositive transfusion) with potential serious complications (Does not alter requirement for reporting under 105 CMR 135.000)
- Poisonings occurring within the facility
- Reportable infectious disease outbreaks
- Serious criminal acts or allegations of abuse occurring within the facility that result in serious harm (physical or mental) to a patient
- Pending staff or supplier strikes that may seriously affect patient services
- Any maternal death within 90 days of delivery or termination of pregnancy
- Death of a patient by suicide

Non-Reportable Incidents - An adverse outcome that is directly related to the natural course of the patient's illness or underlying condition is not reportable. Other non-reportable incidents include, but are not limited to the following:

- Medication errors that do not result in serious complications or diminish the therapeutic value of the medication (e.g., medication given early or late, missed dose)
- Minor reaction to medication or blood transfusion where reactions are controlled with minimum amounts of medication or palliative therapy
- Minor bio-medical device failure or damage resulting in no injury to patient, visitor, or employee
- Patient refuses treatment or procedure or leaves against medical advice
- Incorrect, needle, sponge, or instrument count corrected before surgical procedure is terminated
- Dietary problems that do not affect the patient's status (e.g., food allergy)
- Treatment or procedure error with no residual effect (e.g., routine X-ray or lab test performed without order, or results posted late)
- Surgical procedure error with no residual effect, e.g. which does not require a patient to undergo significant additional diagnostic or treatment measures
- Slips or falls resulting in minor injury (e.g., lacerations)
- Minor injuries of unknown origin

REPORTING PROCEDURES

1. **Telephone Reporting** - Hospitals must immediately report the following incidents to the Department by telephone (105 CMR 130.331(A)):

    - Fire;
    - Suicide;
    - Serious criminal acts;
    - Pending or actual strike;
    - Serious physical injury or harm to a patient resulting from accident or unknown cause;

    Calls during normal business hours should be directed to the Department's intake staff at (617) 753-8150. After hours callers may contact the Department at 522-3700 in the event

of an emergency.

The Department retains the authority to request additional information from the facility, either verbally or in writing

2. **Written Reporting.** Hospitals must within one week report the following incidents to the Department in writing (105 CMR 130.331(B)):

Other serious incidents which seriously affect the health and safety of patients.

The regulation requires a written report of such incidents. We urge hospitals to provide such reports via facsimile according to the procedures listed previously. Written reports should contain the same information as telephone reports. They should either be faxed to 617-753-8165 or mailed to:

Department of Public Health
Division of Health Care Quality
Intake Unit
10 West Street, Fifth Floor
Boston, Massachusetts 02111

The Department does not expect hospitals to report minor incidents or occurrences that do not result in serious injury. Determining the seriousness of physical injury is a responsibility of the hospital. For additional information and questions, please contact Sherman Lohnes at (617) 753-8160.

Nothing reported herein should be construed as absolving the hospital of its reporting obligations to the Board of Registration in Medicine under M.G.L. c. 111 § 203.

INFORMATION TO BE REPORTED

Hospital staff who report incidents via telephone should be prepared to supply the following information:

- Facility Name
- The name, title, and phone number of the reporting individual.
- Incident date and time.
- Patient information to include: name, age, sex, date admitted, ambulatory status, activities of daily living status and cognitive level.
- The type of incident.
- The nature of the harm and the body part affected.
- A brief description of the incident.
- Any safety precautions taken prior to the incident.
- The activity of the patient at the time of the incident, and the location where the incident occurred.

- Any equipment or safety devices in use.
- A brief description of corrective action taken.
- Whether the patient's family and physician were notified, and the physician's name.
- The name and title of the individual in charge of the facility at the time the incident occurred.
- The name and title of any witness(es).